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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,264	09/16/2003	Nicholas W. Warne	22058-544 (AM100664)	1450

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BOSTON, MA 02111

EXAMINER

HISSONG, BRUCE D

ART UNIT	PAPER NUMBER
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1646

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/663,264

Applicant(s)

WARNE ET AL.

Examiner

Bruce D. Hissong, Ph.D.

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 5-12, 17, 19-26 and 28-55 is/are pending in the application.
- 4a) Of the above claim(s) 42-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-12, 17, 19-26, 28-41, 53-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/11/2007 has been entered.

2. Claims 5-12, 17, 19-26, and 28-55 are currently pending. Claims 42-52 are withdrawn as non-elected subject matter. Therefore, claims 5-12, 17, 19-26, 28-41, and 53-55 are the subject of this office action.

Drawings

Objection to the drawing, as set forth on page 3 of the office action mailed on 12/7/2005, and page 2 of the office action mailed on 6/1/2006, is withdrawn in response to Applicants' submission of replacement drawings.

Specification

Objection to the specification for improperly identified trademarks, as set forth on page 3 of the office action mailed on 12/7/2005, and page 2 of the office action mailed on 6/1/2006, is withdrawn in response to Applicants' amendments to the specification to properly identify trademarks.

Claim Objections

Objections to claims 5 and 9, as set forth on page 3 of the office action mailed on 6/1/2007, are withdrawn in response to Applicants' amendments to the claims.

Claim Rejections - 35 USC § 112, first paragraph – enablement and written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 5-12, 17, and 19-26 under 35 USC § 112, first paragraph, regarding lack of enablement and written description for a pharmaceutical composition comprising any interleukin (IL)-11, as set forth on pages 4-6 of the prior office action mailed on 6/1/2006, is withdrawn in response to Applicants' amendments to claim 5 to read only on a composition comprising human IL-11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 5-12, 17, 19-22, 25, 28-41, and 53-55 remain rejected under 35 USC § 103(a) as being obvious in view of the combination of Savastano *et al* ("Savastano") and Greenwood-van Meerveld *et al* ("Greenwood"), as set forth on pages 7-10 of the office action mailed on 6/1/2006.

In the response received on 1/11/2007, the Applicants submitted an affidavit under 37 CFR 1.132 to show that the Greenwood document is not proper prior art because authors Greenwood-van Meerveld and Venkova were members of the Greenwood Group doing work under the supervision of Nicholas Warne, who is an Applicant for the instant application, or his colleague James Keith, who is listed as an author of the Greenwood publication. Mr. Warne asserts that although Mr. Keith was involved in coordinating the testing of the IL-11 formulations, he was not involved in developing the presently claimed compositions or methods of using the compositions. For these reasons, the Applicants assert that the Greenwood

Art Unit: 1646

publication is not prior art, and therefore the instant claims cannot properly be obvious in view of any combination using Greenwood.

These arguments have been fully considered and are not persuasive. The affidavit under 37 CFR 1.132 filed 1/11/2007 is insufficient to overcome the rejection of claims 5-12, 17, 19-22, 25, and 28-41 based upon the combination of Savastano and Greenwood as set forth in the last Office action because the submitted 1.132 declaration is not a statement by an author of the relevant art. To sufficiently overcome the rejection, a statement by author James Keith detailing the role of authors Greenwood-van Meerveld and Venkova is required. A statement by a 3rd party, in this case Mr. Warne, as to the roles of authors on a paper in which he was not an author, is insufficient. Applicants are required, under 37 CFR 1.132, to show that the inventorship of the application is correct in that the reference discloses subject matter invented by the Applicant rather than derived from the author or patentee notwithstanding the authorship of the article or the inventorship of the patent. *In re Katz*, 687 F.2d 450, 455, 215 USPQ 14, 18, (CCPA 1982). Furthermore, where the Applicant is one of the co-authors of a publication cited against his or her application, the publication may be removed as a reference by the filing of affidavits made out by the other authors establishing that the relevant portions of the publication originated with, or were obtained from, the Applicant. *In parte Hirschler*, 110 USPQ 384 (Bd. App. 1952).

2. Claims 23, 24, and 26 remain rejected under 35 USC § 103(a) as being obvious in view of the combination of Savastano *et al* ("Savastano"), Greenwood-van Meerveld *et al* ("Greenwood"), and Porter, as set forth on page 10 of the office action mailed on 6/1/2006.

The Applicants arguments regarding the proper use of Greenwood, and the response to Applicants arguments, are discussed *supra*. The rejection is maintained for the reasons set forth *supra*, and for the reasons of record on page 10 of the previous office action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

Art Unit: 1646

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5, 17, 19-20, 28-31, and 38-39 remain rejected over claim 13 of application no. 10/360,906, as set forth on page 11 of the office action mailed on 6/1/2006. In the response received on 1/11/2007, the Applicants state that they will address the obviousness-type double-patenting rejection if and when they pay the Issue Fee due for the '906 Application.

Conclusion

No claim is allowable.

This is a Request for Continued Examination (RCE) of Applicants' earlier Application No. 10/663,264. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

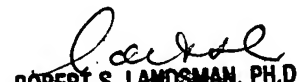
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BDH
Art Unit 1646


ROBERT S. LANDSMAN, PH.D.
PRIMARY EXAMINER